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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,808	12/13/1999	AVI J. ASHKENAZI	P0978-1C1	1650

7590 02/04/2003

ATTN DIANE L MARSCHANG
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SOUTH SAN FRANCISCO, CA 940804990

EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

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DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/459,808

Applicant(s)

ASHKENAZI, AVI J.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 80-87 is/are allowed.
- 6) ☒ Claim(s) 69-78 is/are rejected.
- 7) ☒ Claim(s) 79 is/are objected to.
- 8) ☒ Claim(s) 69-87 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed November 20, 2002 (Paper No. 17) has been entered. Claims 69-87 are pending and being examined to the extent that they read upon the elected species. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

The corrected or substitute drawings were received on November 20, 2002. These drawings are acceptable.

New formal matters, objections, and/or rejections:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5 Claims 69-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,030,945. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed treating blastomas with materials that are identical to the materials used to treat breast, colon, and lung cancers in the patent. A blastoma, as recited in the present

10 claims, is generic to a breast, colon, and lung cancer, as recited in the patent, in the sense that the blastoma is not restricted to breast, colon, or lung, and blastoma encompasses breast, colon, or lung blastomas. A blastoma is a type of cancer. See the present specification at page 12, full paragraph 1, of the present specification. The examiner uses the present specification as dictionary for a definition of the term "blastoma". Accordingly, a breast, colon, or lung blastoma

15 is a type of breast, colon, or lung cancer, respectively. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to treat a breast, colon, or lung blastoma, by administering the materials that are identical in both the present claims and the patent, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to induce apoptosis in the patient's breast, colon, or

20 lung blastoma cells and thereby treat the blastoma.

Claim Rejections - 35 USC § 103

Claims 69, 77, 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiley (25, cited by Applicants). This rejection is based upon an effective filing date of June 29, 1995

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for Wiley. Wiley teaches a soluble TRAIL ligand, which is a fragment of a polypeptide comprising amino acid residues 114-281 of SEQ ID NO: 1 as recited in the present claims, as indicated below:

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5  CC Sequence 2, Application US/09670354
   CC Patent No. 5763223
   CC GENERAL INFORMATION:
   CC APPLICANT: Steven R. Wiley and
   CC INFORMATION FOR SEQ ID NO: 2:
10  CC SEQUENCE CHARACTERISTICS:
   CC LENGTH: 281 amino acids
   CC TYPE: amino acid
   CC TOPOLOGY: linear
   CC MOLECULE TYPE: protein
15  SQ SEQUENCE 281 AA; 32509 MW; 420741 CN;

   Query Match 100.0%; Score 1227; DB 2; Length 281;
   Best Local Similarity 100.0%; Pred. No. 7.88e-109;
   Matches 168; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

20  Db 114 VRERGPQRVAAHITGTRGRSNTLSSPNSKNEKALGRKINSWESSRSGHSFLSNLHLRNGE 173
   Qy 114 VRERGPQRVAAHITGTRGRSNTLSSPNSKNEKALGRKINSWESSRSGHSFLSNLHLRNGE 173

25  Db 174 LVIHEKGFYIYSQTYFRFQEEIKENTKNDKQMQYIYKYTSYPDPILLMKSARNSCWSK 233
   Qy 174 LVIHEKGFYIYSQTYFRFQEEIKENTKNDKQMQYIYKYTSYPDPILLMKSARNSCWSK 233

30  Db 234 DAEYGLYSIYQGGIFELKENDRIFVSVTNEHLIDMDHEASFFGAFLVG 281
   Qy 234 DAEYGLYSIYQGGIFELKENDRIFVSVTNEHLIDMDHEASFFGAFLVG 281,

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fragments of the extracellular domain that retain a desired biological activity (paragraph bridging columns 4-5), and expression of TRAIL polypeptides in bacterial expression systems, such as E. coli, which provides non-glycosylated molecules (column 8, last full paragraph). Wiley is evidence that it is routine to characterize proteins in terms of the minimum size required for activity. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a fragment of a polypeptide consisting of amino acid residues 114-281 of SEQ ID NO: 1, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to obtain a fragments of the extracellular domain that retains a desired biological activity, namely, apoptosis. Wiley also teaches that that TRAIL polypeptides may be employed in treating cancer, including leukemia, lymphoma, and melanoma (column 18, full paragraph 1). Wiley is silent with respect to the treatment of blastoma. However, a blastoma is a type of cancer. See the present specification at page 12, full paragraph 1, of the present specification. The examiner uses the present

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specification as dictionary for a definition of the term "blastoma". It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to treat cancer, including leukemia, lymphoma, and melanoma, with soluble TRAIL polypeptides and fragments thereof, as taught by Wiley, and to modify that teaching by treating blastoma, with a reasonable
5 expectation of success. One of ordinary skill in the art would be motivated to make that modification in order to induce apoptosis in the blastoma cells and treat the blastoma. The invention is prima facie obvious over the prior art.

Claims 69, 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiley (25,
10 cited by Applicants) as applied to claim 69 above, and further in view of Davis (e15).

Wiley teaches the treatment of cancer with TRAIL, as discussed above. Wiley does not teach TRAIL linked to PEG.

Davis discloses that coupling of polypeptides to polyethylene glycol to provides a physiologically active non-immunogenic water soluble polypeptide composition. The
15 polyethylene glycol protects the polypeptide from loss of activity and the composition can be injected into the mammalian circulatory system with substantially no immunogenic response. See the Abstract. Davis does not teach treatment of cancer with TRAIL.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to treat cancer with TRAIL, as taught by Wiley, and to modify that
20 teaching by linking TRAIL to PEG, as taught by Davis, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to provide a physiologically active non-immunogenic water soluble TRAIL composition, protected from

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loss of activity and that can be injected into the mammalian circulatory system with substantially no immunogenic response. The invention is prima facie obvious over the prior art.

Conclusion

5 Claims 80-87 are allowable. Claim 79 is objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37
15 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

25 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

30 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

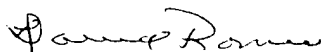
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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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DSR
FEBRUARY 3, 2003